



NDA 20-988/S-004

Wyeth-Ayerst Laboratories  
Attention: Ms. Mary Alice Dankulich  
P.O. Box 8299  
Philadelphia, PA 19101-8299  
Dear Ms. Dankulich:

Please refer to your supplemental new drug application dated May 4, 2001, received May 7, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Protonix<sup>®</sup> I.V. (pantoprazole sodium) for Injection, equivalent to 40 mg.

We acknowledge receipt of your submission dated May 11, 2001.

This "Changes Being Effected" supplemental new drug application provides for adding the following text to the fourth paragraph of the **DOSAGE AND ADMINISTRATION** section to clarify the approved indication and to avoid improper administration of Protonix<sup>®</sup> I.V. for Injection:

“Also, data on safe and effective dosing for other conditions (including life-threatening upper gastrointestinal bleeds) are not available. PROTONIX I.V. 40 mg once daily does not raise gastric pH to levels sufficient to contribute to the treatment of such life-threatening conditions.”

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling (package insert submitted May 4, 2001). Accordingly, the supplemental application is approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2  
FDA  
5600 Fishers Lane  
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please call Cheryl Perry, Regulatory Health Project Manager,  
at (301) 827-7475.

Sincerely,

*{See appended electronic signature page}*

Lilia Talarico, M.D.

Director

Division of Gastrointestinal and Coagulation Drug Products

Office of Drug Evaluation III

Center for Drug Evaluation and Research